



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,033	07/20/2001	Hilary Lackritz	0225-0069.30	3479

33603 7590 08/25/2003

ACLARA BIOSCIENCES, INC.
1288 PEAR AVENUE
MOUNTAIN VIEW, CA 94043

EXAMINER

OLSEN, KAJ K

ART UNIT	PAPER NUMBER
----------	--------------

1753

DATE MAILED: 08/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/911,033

Applicant(s)

LACKRITZ ET AL.

Examiner

Kaj Olsen

Art Unit

1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 6-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-5, drawn to a method of separating ions, classified in class 204, subclass 450.
 - II. Claims 6-8, drawn to a method for sequencing a nucleic acid, classified in class 435, subclass 7.1.
 - III. Claims 9-19, drawn to microfluidic device, classified in class 422, subclass 100.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the sieving polymer could be utilized in a solid frit. The subcombination has separate utility such as for separating protein fragments.
3. Inventions (I or II) and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be utilized for processes not using separation such as flow injection analysis.

Art Unit: 1753

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Jacqueline Mahoney on 8-18-2003 a provisional election was made with traverse to prosecute the invention of group I, claims 1-5. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

7. Claim 1 is objected to because of the following informalities: norbornene is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1753

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Tan et al (US 2002/0029968 A1).
10. With respect to claim 1, Tan discloses a method for separating a mixture of ions in a sample employing a microfluidic device comprising a microchannel having a neutral norbornene based polymer surface and two electrodes for creating an electric field in said microchannel (paragraph 0022 and 0023). The method comprises introducing sample into the microchannel that comprises an aqueous dispersion of a sieving polymer (see abstract) whereby ions in said sample migrate into fractions (paragraph 0003).
11. With respect to claim 2, see paragraph 0077.
12. With respect to claim 3, see paragraph 0023.
13. With respect to claims 4 and 5, see table I on p. 7 and paragraph 0083.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

Art Unit: 1753

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramsey (USP 6,010,608) in view of either Bjornson et al (US 2002/0092767 A1) or Tan.

17. With respect to claim 1, Ramsey discloses a method for separating a mixture of ions in a sample employing a microfluidic device 10 and two electrodes (50, 53) for creating an electric field in said microchannel (paragraph bridging col. 7 and 8). Said method comprises introducing a sample into a microchannel comprising an aqueous dispersion of a sieving polymer (col. 30, lines 26-31) whereby ions in said sample migrate in the aqueous dispersion to separate into fractions (col. 29, line 27 through col. 30, line 13). Ramsey does not explicitly identify the use of a norbornene based polymer for a surface of the microfluidic device. Bjornson discloses in an alternate microfluidic device that a norbornene based polymer is a suitable polymer that strengthens the microfluidic device and favorably alters the electrokinetic flow of the channel (p. 3, paragraph 0026). Tan teaches that norbornene polymers provide low fluorescence emission thereby improving the ability to detect the electrophoretic separation (paragraph 0023). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teachings of either Bjornson or Tan for the apparatus of Ramsey in order to favorably alter the electrokinetic flow of the channels and to provide a substrate with reduced fluorescence background.

Art Unit: 1753

18. With respect to claim 2, see Ramsey, claim 11.
19. With respect to claim 3, see Ramsey, claim 9.
20. With respect to claims 4 and 5, see table I on p. 7 and paragraph 0083 of Tan.
21. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramsey (USP 6,010,608) in view of WO 98/27423 (hereafter "WO '423").
22. With respect to claim 1, Ramsey discloses a method for separating a mixture of ions in a sample employing a microfluidic device 10 and two electrodes (50, 53) for creating an electric field in said microchannel (paragraph bridging col. 7 and 8). Said method comprises introducing a sample into a microchannel comprising an aqueous dispersion of a sieving polymer (col. 30, lines 26-31) whereby ions in said sample migrate in the aqueous dispersion to separate into fractions (col. 29, line 27 through col. 30, line 13). Ramsey does not explicitly identify the use of a norbornene based polymer for a surface of the microfluidic device. WO '423 teaches the use of polynorbornene for structures for carrying out electrophoretic separations, which allows one to favorably alter the properties of the electrophoretic channels (see abstract, p. 1, lines 1-10; and p. 5, lines 6-10). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of WO '423 for the method of Ramsey in order to favorably alter the separation properties of the electrophoretic and electrokinetic channels.
23. With respect to claim 2, see Ramsey, claim 11.
24. With respect to claim 3, see Ramsey, claim 9.
25. With respect to claims 4 and 5, see claims 1-3 of WO '423.

Art Unit: 1753

Conclusion

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kameoka et al discloses the use of norbornene based microfluidic devices, but the reference does not qualify as prior art under 35 U.S.C. 102.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (703) 305-0506. The examiner can normally be reached on Monday through Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Mr. Nam Nguyen, can be reached at (703) 308-3322.

When filing a fax in Group 1700, please indicate in the header "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of this application. This will expedite processing of your papers. The fax number for regular communications is (703) 305-3599 and the fax number for after-final communications is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0661.



Kaj K. Olsen
Patent Examiner
AU 1753
August 22, 2003